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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/017,451	12/18/2001	Octavian Barzu	217489US0	6379
22850	7590	01/12/2004	EXAMINER	
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			MONSHIPOURI, MARYAM	
			ART UNIT	PAPER NUMBER
			1652	

DATE MAILED: 01/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/017,451	Applicant(s) BARZU ET AL.	
	Examiner Maryam Monshipouri	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 9-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-8, 18 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1652

SUPPLEMENTARY RESTRICTION REQUIREMENT

Applicant's response to restriction requirement filed 11/3/2003 is acknowledged. Applicant elected Group I invention directed to claims 1-8 and 18 with traverse. Claims 9-17 are withdrawn as drawn to non-elected invention.

In traversal of restriction requirement applicant argues that the burden of proof is on the Office to provide reasons and/or examples to support any conclusion with regard to patentable distinctness. The Office has neither shown that a burden exists in searching all of the claims nor provided adequate reasons to support a conclusion of patentable distinctness. According to applicant, this is particularly true since the proteins encoded by the elected polynucleotides can be assayed according to the methods of claims 9-17. Hence, according to applicant the restriction should be withdrawn.

These arguments were fully considered but were found **unpersuasive**. Firstly the examiner respectfully disagrees with the applicant that adequate reasons for holding distinctness among the inventions have not been provided by the Office. The examiner requests the applicant to read the previous office action more carefully wherein ample reasons for patentable distinctness among inventions of Groups I-VI are provided. Secondly, the examiner restricted the inventions based on the criteria provided under 35 U.S.C. section 121 in MPEP. The fact that proteins encoded by Group I can be assayed according to methods of Groups II-V, does not provide a criteria for withdrawal of restriction. Further, applicant referred to all claims 9-17 as method claims, which is

Art Unit: 1652

clearly incorrect, as claims 16-17 are directed to modulators (products) and not to methods.

Furthermore, even though there may be some overlap between relevant classes/subclasses between some of the distinct inventions enlisted in the previous office action searches for each group are **not coextensive**. For example, Group I invention requires a search in class 536/23.2 and 435/320.1 which is totally unnecessary for Group II invention. Likewise, Group II invention requires a search in class 530/350 which is totally irrelevant to Group I invention. Therefore, in contrast to applicant's view, rejoining inventions I-VI does impose an undue burden of searching on the examiner.

In conclusion, in view of arguments provided above, in addition to those provided in the previous office action, restriction is maintained and is hereby made **Final**.

Upon further review of the previous office further restriction of Group I invention deemed necessary as shown below:

Group Ia: Claims 1-8 and 18, drawn to *B. subtilis* pyrH gene, vectors and host cells comprising said gene, methods of expressing said gene and methods of purifying said gene product, classified in class 435, subclass 194.

Group Ib; Claims 1-8 and 18, drawn to *H. influenza* pyrH gene , vectors and host cells comprising said gene, methods of expressing said gene and methods of purifying said gene product, classified in class 435, subclass 194.

Art Unit: 1652

Group Ic: Claims 1-8 and 18, drawn to *M. tuberculosis* pyr gene, vectors and host cells comprising said gene, methods of expressing said gene and methods of purifying said gene product, classified in class 435, subclass 194.

The inventions are distinct, each from the other because of the following reasons;

The inventions of Groups Ia-Ic are each directed to a product of independent chemical structure and function.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provision of MPEP section 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after allowance are governed by 37 CFR 1.312.

Art Unit: 1652

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all the criteria for patentability including the requirement of 35 U.S.C. 101, 102, 103 and 112. Until an asserted product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. section 103(b)," 1184 O.G. 86(March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include limitations of the product claim. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP section 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Art Unit: 1652

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maryam Monshipouri whose telephone number is (703)308-1235. The examiner can normally be reached on 7:00 a.m to 5:30 p.m. except for Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnanthapu Achutamurthy can be reached on (703)308-3804. The fax phone number for the organization where this application or proceeding is assigned is (703)308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-0196.

MARYAM MONSHIPOURI, PH.D.
PRIMARY EXAMINER


MARYAM MONSHIPOURI, PH.D.
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